IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 19-2875 Honorable Robert B. Kugler, District Court Judge

SPECIAL MASTER ORDER NO. 91

Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis, LLC, and Actavis Pharma, Inc., (collectively, the "Teva Defendants" or "Teva"), have moved to seal the following documents filed as Exhibits to Plaintiffs' Motion for Class Certification of Consumer Economic Loss Claims (Dkt. 1748):

- TEVA-MDL2875-00049024 (attached as Exs. 16 and 67 to Dkt. 1748)
- TEVA-MDL2875-00549883 (attached as Ex. 66 to Dkt. 1748)
- TEVA-MDL2875-00020519 (attached as Ex. 72 to Dkt. 1748)
- TEVA-MDL2875-00522655 to TEVA-MDL2875-00522660 (attached as Ex. 88 to Dkt. 1748)
- TEVA-MDL2875-00400391 to TEVA-MDL2875-0040000 (attached as Ex. 90 to Dkt. 1748)
- TEVA-MDL2875-00042885 to TEVA-MDL2875-00042887 (attached as

Ex. 97 to Dkt. 1748).

(Dkt. 2197.) In support of its motion Teva has presented the declaration of Anthony R. Binsol, Senior Director/Compliance Lead, Quality Operations Solids Manufacturing Supply Operations for Teva Pharmaceuticals USA, Inc. (Dkt. 2197-4.)[1] Oral argument on the motion to seal was heard on January 4, 2024. (Dkt. 2584.) For the reasons that follow, the motion to seal will be denied.

Document production by Teva in this matter with confidentiality designations permitted by the Protective Order (Dkt. 139) and Amended Protective Order (Dkt. 1661) has been voluminous. Teva represents that it has produced more than 225,000 documents with confidentiality designations. There have been remarkably few challenges to those designations. The confidentiality designations on twenty-three documents were assailed by Plaintiffs and addressed at a hearing on September 13, 2021 and in an Order entered on October 8, 2021, Dkt. 1616. Teva was directed to remove the confidentiality designations on four of the documents in question as well as two attachments to a fifth document. None of the documents at issue in the Fall of 2021, however, was presented to the Court as part of a contested motion.[2]

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[1] Teva's motion is presented pursuant to Local Civil Rule 5.3(c) and the Amended Confidentiality and Protective Order entered in this case on October 21, 2021, Dkt. 1661. Teva's Motion to Seal complies with the procedural requirements of Local Civil Rule 5.3(c).

[2] One of the six documents at issue now, attached as Ex. 90 to Dkt. 1748, was also at issue in the Fall of 2021. It was determined at that time that the confidentiality

The six documents in question now were presented to the Court for adjudicative purposes. Accordingly, they are clothed with a presumption that they should not be sealed, and the public should have access to them. As explained in *In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 924 F.3d 662, 670 (3d Cir. 2019), a "more rigorous common law right of access" applies when, as here, the discovery materials are filed with the court. "In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access." *Id.* (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001).

The right of public access is particularly compelling in class action cases, such as this one, because "many members of the 'public' are also plaintiffs. . . ." *In re Cendant Corp.*, 260 F.3d at 193. Allowing the right to access judicial documents (such as those appended to the Class Plaintiffs' Motions), promotes confidence in the administration of the Class Members' case. *Id.*

Teva thus shoulders a considerable burden to show that disclosure of the information it seeks to shield from public view will cause it to sustain a "clearly defined and serious injury." *Avandia*, 924 F.3d at 678. The "strong presumption of

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designation was proper. That decision, however, did not involve a presumption of public access because the document had not been presented to the Court in the context of a contested motion.

openness does not permit the routine closing of judicial records to the public." *Id.*

The District Court is instructed to "'conduct[] a document-by-document review' of the contents of the challenged documents." "[C]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants." *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993). There must be "*compelling* . . . interests to be protected," and the Court must make "specific findings on the record concerning the effects of disclosure." *In re Cendant*, 260 F.3d at 194 (emphasis added). "Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient." *Id.* Furthermore, sealing must be based on "current evidence to show how public dissemination of the pertinent materials now would cause the competitive harm [alleged]." *Leucadia*, 998 F.2d at 167, quoting *Republic of Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 663(3d Cir. 1991).

Consistent with the Third Circuit's instructions, each of the contested documents has been reviewed in the context of the arguments for sealing articulated by Teva. A document-by-document review follows:

1. TEVA-MDL2875-00049024 (attached as Exs. 16 and 67 to Dkt. 1748): The publicly accessible Declaration of Mr. Binsol describes this document as "an internal investigation report that provides information concerning

Teva's internal reporting, investigative processes, and corrective and preventive actions related to the NDMA and NDEA impurities discovered in Valsartan API manufactured by a Teva supplier." (Dkt. 2197-4 at ¶4.) Mr. Binsol asserts that "disclosure of this document would cause irreparable harm to Teva by providing its competitors with direct insight into Teva's internal processes for investigating, evaluating, correcting, and mitigating the presence of the nitrosamine impurity in Valsartan." (*Id.*) Mr. Binsol further asserts that "disclosure of this document would allow Teva's competitors to identify, replicate, and undercut Teva's internal investigation processes and business strategies, and thereby cause significant competitive harm." (*Id.*) These broad allegations are not linked to any specific part of this document. Teva contends that the document provides a "road map" to its internal review process and its evaluation of its suppliers. (Tr. of 1/4/24 Argument (Dkt. 2584) at 29.) The document, however, simply reports what was done in the wake of the disclosure of the contamination, action that is now largely a matter of public record. No proprietary analytical tests or confidential investigative steps are identified. The report's discussion of "Risk Factors and Analysis" concerns matters already in the public domain, such as the general causes of the nitrosamine contamination. Moreover, as pointed out by Plaintiffs,

Teva was required to undertake the investigation into the nitrosamine contamination and evaluation of its suppliers. *See* Dkt. 2208-2 (FDA March 1, 2019 Letter to Teva). Significantly, Teva does not explain how any of its analytical processes or evaluation of its suppliers differ from the detailed guidance provided by the FDA or the European Medicines Agency ("EMA").[3] Teva has not detailed with the requisite specificity the harm that it could incur if the public has access to this report. Instead, Teva has provided speculation as to how a competitor would view the information in the document. For instance, Teva asserts that "[i]t is when all this information [already in the public domain] is compiled to demonstrate how Teva's internal processes and thought-making and decision-making play out that it becomes something that we feel is competitively sensitive, sufficient to overcome the burden of public access." (Tr. of 1/4/24 Argument (Dkt. 2584) at 36.) This conclusory assertion, bereft of any specific examples or supporting evidence, is insufficient to overcome the presumption of public access.

2. TEVA-MDL2875-00549883 (attached as Ex. 66 to Dkt. 1748): This

[3] The guidance provided by the FDA is found at Dkt. 2208-2 (FDA March 1, 2019 Letter to Teva providing guidance concerning nitrosamine contamination of angiotensin II receptor blockers and testing for the presence of nitrosamine impurities). The EMA guidance is found at Dkt. 2208-3 (EMA June, 2020 report on "nitrosamine impurities in human medicinal products").

document is a "Global Quality Report," current as of July 6, 2018. It is titled "Quality Assessment for Recall Evaluation of Valsartan Single and Combination Products Containing Active Pharmaceutical Ingredient (API): Valsartan, Manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd." The concluding section of this report was read during oral argument followed by the question of how the conclusion could be viewed as a roadmap into Teva's business practices. Counsel responded that one would have to "look back at the rest of the document which shows how Teva arrived at that conclusion." (Tr. of 1/4/24 Argument (Dkt. 2584) at 40.) Teva, however, did not point to any specific part of this 4-page report that provided the type of inside information that could cause competitive harm or give its suppliers insight into how to do business with Teva. The Binsol Declaration merely states that the document "provides comments on Teva's evaluation of a supplier that *may* be competitively sensitive." (Dkt. 2197-4 at ¶5.) Such an equivocal assertion falls far short of the compelling demonstration necessary to warrant sealing a court record. And while the Binsol Declaration maintains that Teva's competitors would gain "direct insight into Teva's internal processes for investigating, evaluating, correcting, and mitigating the presence of nitrosamine impurities in Valsartan," (*id.*), a careful review of the 4-page report does

not reveal how that could be the case.

3. TEVA-MDL2875-00020519 (attached as Ex. 72 to Dkt. 1748): This is an email thread covering the period from June 29, 2018 to July 4, 2018 and involving Teva's Director of Chemical & Computational Toxicology. Teva contends that this email thread "reveals Teva's internal toxicology and risk assessment process related to the presence of NDMA in Valsartan API." (Dkt. 2197-4 at ¶7.) During oral argument, Teva acknowledged that the email chain is "more general than if [Teva's] policy itself were attached and distributed for Teva's competitors to review," and that the email chain "provides a very general roadmap to exactly what Teva is going to do in performing [a] toxicological assessment, what databases they are going to search, the steps that they are going to take and in what order." (Dkt. 2584 at 47.) Teva, however, does not connect disclosure of this "very general roadmap" and "high level discussion" to causing serious competitive harm.

4. TEVA-MDL2875-00522655 to TEVA-MDL2875-00522660 (attached as Ex. 88 to Dkt. 1748): This is an email chain covering the period from October 1, 2018 to October 2, 2018, suggesting edits to a report on a Teva audit of ZHP production processes. Mr. Binsol asserts that disclosure of the email thread "would allow Teva's competitors to identify, replicate,

and undercut Teva's internal processes and business strategies. . . ." (Dkt. 2197-4 at ¶7.) Teva's general assertions are insufficient to support a finding that disclosure of this email thread threatens Teva with the kind of injury that can support the sealing of a court record.

5. TEVA-MDL2875-00400391 to TEVA-MDL2875-0040000 (attached as Ex. 90 to Dkt. 1748): This is an email thread covering the period from October 25, 2018 through October 31, 2018. The subject of this email thread is the concluding section to Teva's audit report for the ZHP facility producing the Valsartan API. The Binsol Declaration repeats the assertion that "disclosure of this document would cause irreparable harm to Teva by providing its competitors with the internal thought processes of Teva leadership concerning an internal audit and Teva's audit processes and internal reporting." The email thread, however, is long on generalizations and short on detailed information. And while the email thread could be read as being critical of a Teva supplier, Teva does not explain how that fact could cause it commercial harm. Although Teva did have a good faith basis for marking this document confidential under the protective order, it has not sustained its burden of rebutting the presumption of public access to this document now that it is part of the court record. *See Cole's Wexford Hotel, Inc. v. Highmark, Inc.*, No. 2:10-

CV-01609-JFC, 2019 WL 3778090, at *12 (W.D. Pa. May 31, 2019) (confidential commercial information is not entitled to absolute exception from public access).

6. TEVA-MDL2875-00042885 to TEVA-MDL2875-00042887 (attached as Ex. 97 to Dkt. 1748): This document contains an email exchange on August 22, 2018, concerning contamination of Valsartan. The email exchange is the result of a notification from Maltese authorities concerning suspected NDEA contamination of Valsartan. Teva again claims that disclosure of the exchange would cause it competitive harm, but it is difficult to discern from the emails that such harm could be incurred. As noted above, Teva must rebut a presumption of access to the email exchange with specific and concrete information. It has not met its burden.

Teva has not rebutted the presumption of public access to the exhibits at issue here. **ACCORDINGLY, IT IS HEREBY ORDERED THAT** Teva's Motion to Seal Exhibits to Plaintiffs' Motion for Class Certification of Consumer Economic Loss Claims (Dkt. 2197) is **DENIED.**

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master